PATHWAY
MEDICAL TECHNOLOGIES

510(k) SUMMARY

DEC - 1 2009

General Information:

Date of Summary Preparation:	November 4, 2009
Name and Address of Manufacturer:	Pathway Medical Technologies, Inc. 10801 120th Ave NE Kirkland, Washington 98033
Contact Person:	Cyndy Adams Regulatory Affairs Sr. Manager Phone: 425-636-4047 Fax: 425-636-4001
Trade Name:	Jetstream G3™ System
Common Name:	Peripheral Atherectomy Catheter
Regulation Number:	21 CFR 870.4875
Regulation Name:	Intraluminal Artery Stripper
Regulatory Class:	Class II
Classification Panel:	Cardiovascular
Product Code:	MCW
Predicate Devices:	Manufacturer: Pathway Medical Technologies, Inc. (1) Jetstream G3™ System (K092332)

Indications for Use: The Jetstream G3™ System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries ≥3.0 mm in diameter. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Device Description: The Jetstream G3 System is an atherectomy catheter system designed with an expandable cutting tip for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through a port in the Catheter tip to a collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

The Jetstream G3 System consists of two primary components: (1) a Catheter with Control Pod and (2) a Console, which are packaged separately. Each of these system components is described generally as follows:

- **Jetstream G3 Catheter with Control Pod:** A sterile, single-use unit consisting of an electrically driven Catheter and Control Pod. The Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities. The Control Pod provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a double-pouched tray.

- **PV Console:** A reusable compact Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

This 510(k) is for the same device most recently cleared under 510(k) K092332, but changes the motor gear ratio to increase torque and improve cutting efficiency of the device.

Substantial Equivalence: The Jetstream G3 System is substantially equivalent to the specified predicate device. The device has the identical indications for use and the same technological characteristics. Bench testing was completed and provided to support the safety and effectiveness of the modifications that were the subject of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC - 1 2009

Pathway Medical Technologies, Inc.
c/o Ms. Cyndy Adams
Regulatory Affairs Sr. Manager
1080 120th Avenue NE
Kirkland, WA 56033

Re: K093456
Jetstream G3 system
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: November 4, 2009
Received: November 5, 2009

Dear Ms. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093456

Device Name: Jetstream G3™ System

Indications for Use: The Jetstream G3™ System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries ≥ 3.0 mm in diameter. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093456